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DAVIDSON, DAVIDSON & KAPPEL, LLC
14th Floor
485 Seventh Avenue
New York, NY 10018

EXAMINER
ALSTRUM ACEVEDO, JAMES HENRY

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1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/701,041	OSHLACK ET AL.	
	Examiner	Art Unit	
	JAMES H. ALSTRUM ACEVEDO	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *62-85* is/are pending in the application.

4a) Of the above claim(s) *68* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *62-67 and 69-85* is/are rejected.

7)☒ Claim(s) *65 and 69* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/10/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 62-85 are pending. Applicants previously cancelled claims 1-61. Applicants have amended claims 62-63, 65-66, 69-70, and 73-74. Claim 68 is withdrawn from consideration as being drawn to a non-elected species. Claims 75-85 are new. **Claims 62-67 and 69-85 are under consideration in the instant office action**. Receipt and consideration of Applicants' amended claim set and remarks/arguments submitted on September 12, 2008 are acknowledged. All rejections/objections not explicitly maintained in the instant office action have been withdrawn per Applicants' claim amendments, specification amendments, and/or persuasive arguments.

Election/Restrictions

The species election requirement mailed on 3/2/07 is maintained at this time.

Claim Objections

Claims 65 and 69 are objected to because of the following informalities: the word "from" is misspelled as "form" on line 3 of claim 65 and line 4 of claim 69. Appropriate correction is required.

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 84 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement (new matter). The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants' have indicated that the limitations of new claim 84 are supported on page 66, lines 20-23 of the specification (reproduced below).

EXAMPLE 19

This is a randomized single blind, single dose, placebo controlled 10-way crossover trial examining the effect of naltrexone on the subjective and physiological effects of 15 mg hydrocodone in 16 normal subjects. Doses of naltrexone ranged from 0.4 to 12.8 mg. In this study, 0.4 mg of naltrexone was able to antagonize several of the centrally mediated opioid effects of hydrocodone, including pupillary miosis. Based on this data, substantially lower doses below 0.25 mg of naltrexone will demonstrate little antagonism of the concomitant agonist. This is supported by the absence of withdrawal signs observed in subjects in example 17 receiving the 0.25-mg.

The clinical data for examples 17, 18 and 19 suggest that bio-available, immediate-release doses of 0.125 mg of naltrexone (or equivalent prompt release from a controlled release dosage form) will not affect analgesia to any significant degree, while larger prompt release of bio-available drug (0.25 mg or greater) will do so. These clinical data show that a loading of naltrexone into the opioid matrix for this example at a ratio of 1:15 to 1:30 mg naltrexone/mg hydrocodone, and that the tampered/intact release ratio is at least 4:1 and preferably higher. Or alternatively, it can be defined that less than 0.25 mg of naltrexone is released from the intact dosage form, and 0.25 mg or greater naltrexone is released from the crushed dosage form.

The Examiner respectfully disagrees, because the cited portion of Applicants' specification merely indicates that a bio-available dose of 0.125 mg of naltrexone will not affect analgesia to any significant degree. Applicants' claim 84 recites that the amount of antagonist released is less than an amount bioequivalent to 0.125 mg of naltrexone. Bio-availability is not synonymous with bioequivalence and Applicants' citation only provides support for the release of an amount of naltrexone of less than 0.25 mg.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 65-67, 69-72, 77-78, and 81-85 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-33 and 39-40 of U.S. Patent No. 6,696,088 (USPN '088). Although the conflicting claims are not identical, they

are not patentably distinct from each other because the rejected claims represent an obvious variant of the claimed oral dosage forms of USPN '088 reciting a "means for sequestering the opioid antagonist." Claim 65 of the instant application claims a composition comprising (1) opioid agonist and (2) an opioid antagonist composition comprising (a) an inert core, (b) a first layer consisting of an opioid antagonist, (c) a second layer comprising a hydrophobic material, wherein the first layer is located between the inert core and the 2nd layer. Dependent claims 6 and 13-33 of USPN '088 claim an oral dosage form comprising (a) an opioid agonist (e.g. hydrocodone, codeine, oxycodone, morphine, etc.), (b) an opioid antagonist (i.e. naltrexone, naloxone, nalmefene, cyclazocine, or levallorphan) and (c) a means for sequestering the opioid antagonist, characterized by the property that 36% or less of the antagonist is released after 36 hours from the intact dosage form.

The difference between the claims of USPN '088 and the rejected claims is that the claims of USPN '088 do not specify that the means of sequestering the opioid antagonist includes particles comprising (a) an inert core, (b) a first layer consisting of an opioid antagonist, (c) a second layer comprising a hydrophobic material, wherein the first layer is located between the inert core and the 2nd layer. Looking to the specification of USPN '088 to understand the meaning of the phrase "a means for sequestering the opioid antagonist" it is concluded that said means was contemplated to include an opioid antagonist composition comprising (a) an inert core, (b) a first layer consisting of an opioid antagonist, (c) a second layer comprising a hydrophobic material, wherein the first layer is located between the inert core and the 2nd layer (see, for example, Example 25 or col. 19, line 17 through col. 27, line 23). It is noted that the specification of USPN '088 does not define the phrase, "a means for sequestering the opioid

antagonist." It is proper to utilize the specification of an issued US patent or a copending US patent application to ascertain the meaning of terms and to ascertain what would be an obvious variant of claimed subject matter. This position is supported by the courts. *See In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *See also* MPEP §804 (indicating that the specification can be used as a dictionary and that those portions of the specification that provide support for claims may be used to determine what constitutes an obvious variant).

Regarding the properties recited in new claims 77-78 and 81-85, these properties are considered to be present in the claimed dosage forms of USPN '088. Therefore, a person of ordinary skill in the art at the time of the instant invention would have found claims 65-67, 69-72, 77-78, and 81-85 *prima facie* obvious over claims of 1-33 and 39-40 USPN '088.

Claims 62-63 **remain provisionally rejected** on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 41 of copending Application No. 10/401,111 (copending '111) for the reasons of record, which have been restated below. **Claims 75-76, 79-80, and 83-85 are appended to this rejection** for the reasons of record.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the cited claims of both applications are substantially overlapping in scope and mutually obvious. Independent claim 62 of the instant application has been described above in the instant office action. Independent claim 41 of copending '111 an oral dosage form comprising (i) an inert core, (ii) a 1st layer, and (iii) a 2nd layer, the 1st layer being between the core and the 2nd layer and comprising a mixture of naltrexone hydrochloride and a stabilizer, and the second layer comprising a mixture of gelatin and a hydrophobic material. Therefore, a person

of ordinary skill in the art at the time of the instant invention would have found claims 62-63 of the instant application *prima facie* obvious over claim 41 of copending Application No. 10/401,111 (copending '111). Regarding the properties recited in new claims 77-78 and 81-85, these properties are considered to be present in the claimed dosage forms of

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 62-64 **remain provisionally rejected** on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-3 and 15-17 of copending Application No. 10/524,334 (copending '334) for the reasons of record, which have been restated below. **Claims 75-76, 79-80, and 83-85 are appended to this rejection** for the reasons of record.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the cited claims of both applications are substantially overlapping in scope and mutually obvious. Independent claim 62 of the instant application has been described above in the instant office action. Independent claim 1 of copending '334 an oral dosage form comprising (i) a substrate comprising an opioid antagonist (e.g. an inert core, such as is recited in claims 2-3 of copending '334) (ii) a diffusion barrier coating comprising an anionic polymer over said substrate layer, and (iii) a coating comprising a hydrophobic material coated over said diffusion barrier coating. Dependent claims 15-16 of copending '334 further specify the nature of the coating material as being a hydrophobic material that provides sequestration of the opioid antagonist. Dependent claim 17 of copending '334 claims the pharmaceutical formulation of claim 1, wherein the opioid antagonist is selected from the group consisting of naltrexone,

naloxone, and pharmaceutically acceptable salts thereof. Therefore, a person of ordinary skill in the art at the time of the instant invention would have found claims 62-64 of the instant application *prima facie* obvious over claims 2-3 and 15-17 of copending Application No. 10/514,334 (copending '334).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments to Above Provisional Obviousness-Type Double Patenting Rejections

Applicant's arguments filed 9/12/08 have been fully considered but they are not persuasive. Applicants have not provided any substantive arguments traversing the above-maintained provisional obviousness-type double patenting rejection, but have merely stated an intention to consider filing terminal disclaimers upon indication that the claims are allowable. Thus, the above rejections are maintained at this time, because no substantive arguments were presented traversing these rejections.

Claims 65-67, 69-74, 77-78, and 81-85 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 19, 21, 24-26, 59- and 63 of copending Application No. 10/689,866 (copending '866)[1]. Although the conflicting claims are not identical, they are not patentably distinct from each other because the rejected claims represent an obvious variant of the claimed compositions of copending '866 and/or the rejected claims are suggested by the claims of copending '866. Claim 65 of the instant

application claims a composition comprising (1) opioid agonist and (2) an opioid antagonist composition comprising (a) an inert core, (b) a first layer consisting of an opioid antagonist, (c) a second layer comprising a hydrophobic material, wherein the first layer is located between the inert core and the 2nd layer. Independent claims 1-2 of copending '866 claim an oral dosage form comprising (i) an opioid agonist in releasable form, (ii) particles of a sequestered opioid antagonist, and (iii) a sequestering material, substantially preventing the release of the antagonist from the dosage form and separating the antagonist from the agonist. Independent claim 7 of copending '866 is similar to claims 1-2 of copending '866 and specifies that the formulation provides analgesia. It is prima facie obvious to administer a formulation that provides analgesia to treat pain, because analgesics are conventionally used to treat pain.

The difference between the claims of copending '866 and the rejected claims is that the claims of copending '866 do not specify (i) the opioid antagonist and (ii) do not specify how the opioid antagonist is sequestered by the hydrophobic material. Looking to the specification of copending '866 to understand the metes and bounds of the sequestering effect of the hydrophobic material, it is concluded that an opioid antagonist composition comprising (a) an inert core, (b) a first layer consisting of an opioid antagonist, (c) a second layer comprising a hydrophobic material, wherein the first layer is located between the inert core and the 2nd layer (see, for example, Example 25 or col. 19, line 17 through col. 27, line 23) was contemplated as the means by which the hydrophobic material would sequester an opioid antagonist when added to a solid dosage form comprising an opioid agonist. Regarding the opioid antagonist, the specific antagonists recited in Applicants' claims were contemplated in the claims of copending '866, as

[1] Copending '866 has the identical specification as the instant application, because both are continuations of the

evidenced by dependent claim 21 of copending '866, for example. It is proper to utilize the specification of an issued US patent or a copending US patent application to ascertain the meaning of terms and to ascertain what would be an obvious variant of claimed subject matter. This position is supported by the courts. *See In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *See also* MPEP §804 (indicating that the specification can be used as a dictionary and that those portions of the specification that provide support for claims may be used to determine what constitutes an obvious variant).

Regarding the properties recited in new claims 77-85, these properties are considered to be present in the claimed dosage forms of copending '866. Regarding the amount of hydrophobic material in the suggested compositions, this amount would clearly be varied upon varying the amount of the particles comprising hydrophobic material and opioid antagonist. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention. Therefore, a person of ordinary skill in the art at the time of the instant invention would have found claims 65-67, 69-74, 77-78, and 81-85 *prima facie* obvious over claims 1-7, 19, 21, 24-26, 59-and 63 of copending Application '866.

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same parent application.

Claims 65-67, 69-72, and 75-85 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 62, 64, and 70-82 of copending Application No. 10/700,893 (copending '893). Although the conflicting claims are not identical, they are not patentably distinct from each other because the rejected claims represent an obvious variant of the claimed compositions of copending '893 and/or the rejected claims are suggested by the claims of copending '893." Claim 65 of the instant application claims a composition comprising (1) opioid agonist and (2) an opioid antagonist composition comprising (a) an inert core, (b) a first layer consisting of an opioid antagonist, (c) a second layer comprising a hydrophobic material, wherein the first layer is located between the inert core and the 2nd layer. Independent claim 62 of copending '893 claims a composition comprising an opioid antagonist and from about 93% to about 98% of a hydrophobic material, such that when the composition is added to a solid dosage form containing an opioid agonist, the hydrophobic material sequesters the opioid antagonist.

The difference between the claims of copending '893 and the rejected claims is that the claims of copending '893 do not specify (i) the opioid antagonist and (ii) do not specify how the opioid antagonist is sequestered by the hydrophobic material. Looking to the specification of copending '893[2] to understand the metes and bounds of the sequestering effect of the hydrophobic material, it is concluded that an opioid antagonist composition comprising (a) an inert core, (b) a first layer consisting of an opioid antagonist, (c) a second layer comprising a hydrophobic material, wherein the first layer is located between the inert core and the 2nd layer (see, for example, Example 25 or col. 19, line 17 through col. 27, line 23) was contemplated as

the means by which the hydrophobic material would sequester an opioid antagonist when added to a solid dosage form comprising an opioid agonist. Regarding the opioid antagonist, the specific antagonists recited in Applicants' claims were contemplated in the claims of copending '893, as evidenced by the disclosure on page 24, lines 10-14 of the specification of copending '893. It is proper to utilize the specification of an issued US patent or a copending US patent application to ascertain the meaning of terms and to ascertain what would be an obvious variant of the claimed subject matter. This position is supported by the courts. *See In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *See also* MPEP §804 (indicating that the specification can be used as a dictionary and that those portions of the specification that provide support for claims may be used to determine what constitutes an obvious variant).

Regarding the properties recited in new claims 77-85, these properties are considered to be present in the claimed dosage forms of copending '893. Therefore, a person of ordinary skill in the art at the time of the instant invention would have found claims 65-67, 69-72 and 75-85 *prima facie* obvious over claims 62, 64, and 70-82 of copending Application '893.

Claims 62-63 and 65-67, and 75-85 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 75-78, 80, and 87-91 **of copending Application No. 10/700,906 (copending '906)[3].** Although the conflicting claims are not identical, they are not patentably distinct from each other because the rejected claims represent an obvious variant of the claimed dosage forms of copending '906, especially

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[2] Copending '893 has the identical specification as the instant application, because both are continuations of the same parent application.

[3] Copending '906 has the identical specification as the instant application, because both are continuations of the same parent application.

regarding the "means for sequestering the opioid antagonist". Claim 65 of the instant application claims a composition comprising (1) opioid agonist and (2) an opioid antagonist composition comprising (a) an inert core, (b) a first layer consisting of an opioid antagonist, (c) a second layer comprising a hydrophobic material, wherein the first layer is located between the inert core and the 2nd layer. Claim 62 of the instant application claims a composition free of an opioid agonist as described by item (2) in the above description of claim 65. Independent claim 75 of copending '906 claims an oral dosage form comprising (i) particles consisting of an opioid antagonist and (ii) a means for sequestering the opioid antagonist, substantially preventing the release of the antagonist from the intact dosage form, unless said dosage form has been tampered with. Dependent claim 76 of copending '906 specifies that the means for sequestering comprises a layer comprising a hydrophobic material.

The difference between the claims of copending '906 and the rejected claims is that the independent claims of copending '906 do not specify (i) the opioid antagonist and (ii) do not specify how the opioid antagonist is sequestered by the hydrophobic material. Looking to the specification of copending '906 to understand the metes and bounds of the sequestering effect of the hydrophobic material, it is concluded that an opioid antagonist composition comprising (a) an inert core, (b) a first layer consisting of an opioid antagonist, (c) a second layer comprising a hydrophobic material, wherein the first layer is located between the inert core and the 2nd layer (see, for example, Example 25 or col. 19, line 17 through col. 27, line 23) was contemplated as the means by which the hydrophobic material would sequester an opioid antagonist present in a solid dosage form. Regarding the opioid antagonist, the specific antagonists recited in

Applicants' claims were contemplated in the claims of copending '906, as evidenced by dependent claim 78 of copending '906, for example. It is proper to utilize the specification of an issued US patent or a copending US patent application to ascertain the meaning of terms and to ascertain what would be an obvious variant of claimed subject matter. This position is supported by the courts. *See In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *See also* MPEP §804 (indicating that the specification can be used as a dictionary and that those portions of the specification that provide support for claims may be used to determine what constitutes an obvious variant).

Regarding the properties recited in new claims 75-85, these properties are considered to be present in the claimed dosage forms of copending '906. Therefore, a person of ordinary skill in the art at the time of the instant invention would have found claims 62-63 and 65-67, and 75-85 *prima facie* obvious over claims 75-78, 80, and 87-91 of copending Application '906.

Conclusion

Claims 62-67 and 69-85 are rejected. Claims 65 and 69 are objected. No claims under consideration in the instant office action are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

J.H.A.-A.
Patent Examiner
Technology Center 1600

/Johann R. Richter/
Supervisory Patent Examiner, Art Unit 1616